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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,096	12/31/2003	John H. Cafarella	64154-015(RRAK-3)	9612
7590 Toby H. Kusmer, P.C. McDERMOTT, WILL & EMERY 28 State Street Boston, MA 02109			EXAMINER ABRAHAM, SALIEU M	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 11/23/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/750,096

**Applicant(s)**

CAFARELLA, JOHN H.

**Examiner**

Salieu M. Abraham

**Art Unit**

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-162 is/are pending in the application.
- 4a) Of the above claim(s) 22-79, 102-162 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 80-101 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/31/2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 09/03/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I, species #1, drawn to claims 1-21 and 80-101 in the reply filed on 10/1/2007 is acknowledged.
2. Claim 22-79 and 102-162 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/1/2007.

### *Specification*

3. The disclosure is objected to because of the following informalities: in section 0034, the word "doubting" needs to be replaced with "doubling".

Appropriate correction is required.

### *Claim Objections*

4. Claims 97, 100 and 101 objected to because of the following informalities:
  - a. **Re claim 97** – the claim is a duplicate of claim 96.

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- b. **Re claims 100 and 101** – the claim preambles are incorrect. They should start with “A System”, not “A Method”.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. Claims 1 – 2, 9-20, 80 - 81 and 88-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,264,610 to Zhu (Zhu).

In Reference to Claims 1 and 80

**Zhu** discloses all limitations for method claim1 and corresponding system claim 80 with the exception of “acquiring spatial data with respect to the region of interest **using at least three separate probing methods**”; technically, Zhu uses two probing methods (one optical and a B-mode ultrasound). Applicant’s limitation of using three ultrasound modalities instead of one is merely duplication and does not distinguish over the invention of Zhu.

Therefore, in view of the Zhu disclosure (see column 7, lines 12-24) it would be obvious

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to one of ordinary skill that his multimodal system could be modified or adapted to incorporating more probing methods without deviating from the scope of the invention: using multimodal imaging to provide both physiological and diagnostic data for enhancing "the ability to distinguish a tumor from normal tissue" (see column 7, lines 9-12).

Specifically Zhu discloses:

**(Re claim 1):** A method of detecting the presence of malignant tissue within a region of interest within a living body, wherein the malignant tissue is characterized by one or more physical manifestations differentiating it from normal tissue, comprising: (see column 7, lines 9-12)

a) acquiring spatial data with respect to the region of interest using at least three separate probing methods, each probing method being of the type that senses the presence of malignant tissue within the region of interest by sensing at the presence of a physical manifestation associated with the malignant tissue; (see abstract and claims 1,2 and 6)

and

b) co-registering the acquired spatial data from all of the probing methods so as to improve the receiver operating characteristics of detection performance (see abstract and columns 6, lines 66-67 and 7, lines 1-12)

**(Re claim 80):** A system for detecting the presence of malignant tissue within a region of interest within a living body, wherein the malignant tissue is characterized by one or more physical manifestations differentiating it from normal tissue, comprising: (see column 7, lines 9-12)

a) a data acquisition subsystem constructed and arranged so as to acquire spatial data with respect to the region of interest using at least three separate probing

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methods, each sensing modality being of the type that senses the presence of malignant tissue within the region of interest by sensing at the presence of a physical manifestation associated with the malignant tissue; (see claim 6 and column 7, lines 9-12)

and

b) a data registration subsystem constructed and arranged so as to co-register the acquired spatial data from all of the probing methods so as to improve the receiver operating characteristics of detection performance. (see claims 7 and 11 columns 6, lines 66-67 and 7, lines 1 - 12)

In Reference to Claims 2 (Method) and 81 (System)

**Zhu** further discloses:

(**Re claim 2**): A method of claim 1, wherein at least one of the probing methods is ultrasonic, and acquiring spatial data includes receiving backscattered signals from the tissue. (see abstract and claim 6)

(**Re claim 81**): A system of claim. 80, wherein at least one of the probing methods is ultrasonic, and the data acquisition subsystem includes a receiver constructed and arranged so as to receive backscattered signals from the tissue. (see abstract and claim 6)

**Therefore**, Zhu meets all claim 2 and 81 limitations.

In Reference to Claims 9 (Method) and 88 (System)

**Zhu** been shown to teach all claim1 and 80 limitations. Zhu further discloses:

(**Re claim 9**): A method of claim 1, further including interpreting the co-registered data.

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(see column 1, lines 57-67)

**(Re claim 88):** A system of claim 80, further including a data interpreter constructed and arranged so as to interpret the co-registered data. (see figure 4 and column 5, lines 1-9).

**Therefore,** Zhu meets all claim 9 and 88 limitations.

In Reference to Claims 10-11 (Method) and 89-90 (System)

**Zhu** been shown to teach all claim 8 and 88 limitations. Zhu further discloses:

**(Re claim 10):** A method of claim 9, wherein interpreting the co-registered data includes automatically detecting data indicating the presence of malignant tissue within the region of interest. (see figure 4, column 6, lines 12-36 and column 7, lines 2-12)

**(Re claim 89):** A system of claim 80, further including a data interpreter constructed and arranged so as to interpret the co-registered data. (see figure 4, reference marks 106 and 108)

**Therefore,** Zhu meets all claim 10 and 89 limitations.

**(Re claim 11):** A method of claim 9, wherein interpreting the co-registered data includes generating the co-registered data as image data. (see column 7, lines 1-12)

**(Re claim 90):** A system of claim 89, wherein the data interpreter is constructed and arranged so as to generate the co-registered data as image data. (see claims 15-18 and column 5, lines 4-9)

**Therefore,** Zhu meets all claim 11 and 90 limitations.

In Reference to Claims 12 (Method) and 91 (System)

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**Zhu** been shown to teach all claim 11 and 90 limitations. Zhu further discloses:

**(Re claim 12):** A method of claim 11, wherein the data acquired by each modality is represented by a different color so that tissue within the region of interest is represented by a pseudo color representation. (see column 6, lines 47-49 and claim 17)

**(Re claim 91):** A system of claim 90, wherein the data acquired by each modality is represented by different color so that image data of tissue within the region of interest is represented by a pseudo color representation. (see claims 17 and 18)

**Therefore,** Zhu meets all claim 12 and 91 limitations.

In Reference to Claims 13 (Method) and 92 (System)

**Zhu** been shown to teach all claim 1 and 80 limitations. Zhu further discloses:

**(Re claim 13):** A method of claim 1, wherein acquiring spatial data includes using a hand-held instrument positioned so as to be stationary relative to the region of interest during the acquisition of such spatial data. (see figure 3, reference mark 10 and column 2, lines 49-64)

**(Re claim 92):** A system of claim 80, wherein the data acquisition subsystem includes a hand-held instrument positioned so as to be stationary relative to the region of interest during the acquisition of such spatial data. (see figure 3, reference mark 10 and column 2, lines 49-64)

**Therefore,** Zhu meets all claim 13 and 92 limitations.



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In Reference to Claims 15-16 (Method) and 94-95 (System)

**Zhu** has been shown to teach all claim 1 and 80 limitations. Zhu further discloses that the transceiver array may be of different (multi-) dimensions. (see claims 2 and 3).

**Therefore**, Zhu meets all claims 15-16 and 94-95 limitations.

In Reference to Claim 17 (Method) and 96 (System)

**Zhu** been shown to teach all claim 1 and 80 limitations. Zhu further discloses the well known dual benefits of contrast afforded by optical methods such as NIR and resolution afforded by ultrasound for detecting with high specificity cancerous tissue. M-of-N detection is a routine and well known protocol employed in the pattern recognition or sample screening/detection arenas for providing a reasonable level of confidence regarding accuracy of screening results such as applicant refers to regarding his proposed invention. It would be obvious to one of ordinary skill that a likelihood of M-of-N detection would be included for the tumor detection scheme of applicant.

**Therefore**, Zhu meets all claim 17 and 96 limitations.

**Note:** Claim 97 is a duplicate of claim 96 (see claim objections).

In Reference to Claim 18 (Method) and 98 (System)

**Zhu** has been shown to teach all claim 1 and 80 limitations. Zhu further discloses a system and method encompassing an exemplary B-mode ultrasound probing method. However, Zhu, unlike applicant, is not detecting blood flow. Doppler ultrasound is a well known blood flow detection ultrasound modality. Therefore, one of ordinary skill would expect that it would be the ultrasound mode of choice for any application involving the detection of blood flow.

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**Therefore**, Zhu meets all claim 18 and 98 limitations.

In Reference to Claims 19 (Method) and 99 (System)

**Zhu** been shown to teach all claim 1 and 80 limitations. Zhu further discloses a system and method "wherein at least one of the probing methods is electromagnetic probing of dielectric permittivity. (see abstract and column 6, lines 20-30 and lines 36-40).

**Therefore**, Zhu meets all claim 19 and 99 limitations.

In Reference to Claim 20 (Method) and 100 (System)

**Zhu** has been shown to teach all claim 1 and 80 limitations. Zhu further discloses a system and method encompassing at least one probing method of diffusive IP probing of tissue (see abstract and claims 1 and 15).

**Note:** Claim 100 was interpreted as "A system of claim 80" and not "A method of claim 80" as stated (see claim objections).

7. Claims 3 – 4, 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,264,610 to Zhu (Zhu) in view of US Pat. No. 4,509,368 to Whiting (Whiting).

In Reference to Claims 3-4 (Method) and 82-83 (System)

**Zhu** has been shown to teach all claim 1 and 80 limitations. However, Zhu fails to teach:

**(Re claim 3):** "A method of claim 1, wherein at least one of the probing methods is ultrasonic, and acquiring spatial data includes receiving transmitted signals through the tissue in the region of interest", and

**(Re claim 82):** "A system of claim 80, wherein at least one of the probing methods is ultrasonic, and the data acquisition subsystem includes a receiver constructed and arranged so as to receive transmitted signals through the tissue in the region of interest."

**Whiting, in the same field of endeavor**, discloses a system and method for ultrasound tomography for use in clinical diagnostics comprising paired couples of transmission and reflection transducers (see abstract). He cites that this approach allows for significant improvements in speed and accuracy of data acquisition (see abstract and column 3, lines 16-24).

**Therefore**, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the transmission signal reception capability (apparatus and method) of Whiting in the system and method of Zhu in order to "provide a rapid, more reliable technique for non-invasive" diagnostics that make use of ultrasound as explicitly taught by Whiting.

**(Re claims 4 and 83):** **Zhu** has been shown to teach all claim1 limitations. Furthermore, Whiting has been shown to teach a system and method that is capable of receiving both " backscattered and transmitted signals through the tissue in the region of interest". (see abstract and column 4, lines 1-46).

**Therefore**, Zhu in view of Whiting meets all claim 4 and 83 limitations.

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8. Claims 5-8, 21, 84-87 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,264,610 to Zhu (Zhu) in view of US Pat. No. 5,713,356 to Kruger (Kruger).

In Reference to Claims 5 (Method) and 84 (System)

**Zhu** been shown to teach all claim 1 and 80 limitations. However, Zhu fails to disclose:

(**Re claim 5**): "A method of claim 1, wherein acquiring spatial data with respect to the region of interest includes compounding so as to acquire independent samples of an image point so as to reduce speckle".

(**Re claim 84**): "A system of claim 80, wherein the data acquisition subsystem is further constructed and arranged so as to acquire independent samples of an image point so as to compound data and reduce speckle".

**Kruger, in the same field of endeavor**, discloses a system and method for using energy in the electromagnetic spectral domain for sampling and analysis of biologic tissues in vivo, particularly the breasts (see abstract). Kruger further discloses (compounding so as to reduce speckle) "obtaining independent samples of an image point" by respectively using different ultrasonic carrier frequencies or/and different angular aspects (see figures 1 <system>, 3, 4 and 15 <method>) in order to produce a medically useful diagnostic image from the tissue, which are the direct result of sonic waves (see abstract and claims 1 and 2).

**Therefore**, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the system and method of compounding so as to reduce speckle of Kruger in the system and method of Zhu in order to produce a medically useful diagnostic image from a region of interest as explicitly taught by Kruger.

In Reference to Claims 6-8 (Method) and 85-87 (System)

**Zhu** in view of Kruger has been shown to teach all claim 5 and 84 limitations. Additionally, it was also shown that Kruger teaches the claims 6-8 and 85-87 limitations of using ultrasound wave disparate frequencies and angulations to reduce speckle and compose/construct images of the target region in vivo (see abstract, figure 1, column 3, lines 9-60 and column 14, lines 7-37).

**Therefore**, Zhu in view of Kruger meets all claims 6-8 and 85-87 limitations.

In Reference to Claims 21 (Method) and 101 (System)

**Zhu** been shown to teach all claim 1 and 80 limitations. Kruger further discloses a system and method "wherein at least one of the probing methods is photo-acoustic probing of tissue properties. (see abstract and figure 15).

**Therefore**, Zhu in view of Kruger meets all claim 21 and 101 limitations.

***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anselmo et al., Casscells et al., Fiesler et al., Jeon et al., Nelson et al. and Nutt have been included because they all teach the use of multimodal diagnostic in vivo tissue systems and methods similar in scope to applicant's proposed invention.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 9:30 am - 7:00 pm EST.

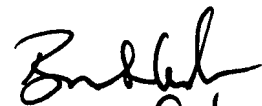
If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/2/07 SA

  
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